

Protective Cover for Medical Devices

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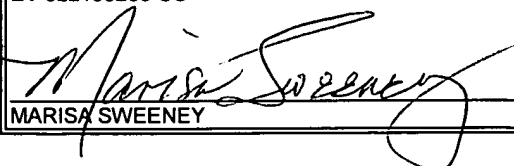
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PROTECTIVE COVER FOR MEDICAL DEVICES

FIELD OF THE INVENTION

The present invention relates to protective covers for medical devices including catheters,
5 gastro-intestinal tubes, nephrostomey tubes, abscess drains, common bile duct tubes, feeding
tubes, stomach feeds and other partially exposed devices which may be implanted in or during
medical procedures.

BACKGROUND

In the medical arts, many kinds of medical devices are used in connection with health care
10 procedures and treatment programs. By way of example, central catheters, of which there are
many examples of varying designs, are partially implanted into a patient so that a portion is
lodged within the body, specifically such that the tip is inserted into the bottom two-thirds of the
superior venacava (which is the largest vein in the human body). These catheters are often
used in a variety of medical treatments, such as by way of example, hemodialysis, stem cell
15 retrieval and some chemotherapies.

After the catheter or other medical device is implanted, a portion of the catheter (or other
device) is exposed, outside of the patient's body. The exposed portion of the catheter, or other
medical device, should be kept dry, clean and protected to provide comfort and avoid
contamination or other accidental injury to the patient. In the past, nurses and other medical
20 staff have devised make-shift dressings and coverings, typically using gauze and medical
adhesive tapes to prepare protective wrappings about the exposed devices. Although such
makeshift devices may provide some protective benefits, various problems may arise.
Makeshift coverings are prone to substantial variation due to differences introduced by
individual application techniques, variations found in the medical supplies used to make the
25 coverings and other factors. By way of example, these earlier coverings are difficult to remove
with the combination of adhesive tape and gauze dressing adhering to the patient so that upon
removal of the coverings, the catheter or other medical device could pull away from the patient
causing pain, injury and additional long term discomfort and other possible complications to the
patient.

30 These earlier coverings were made of materials which did not offer protection against water
contact or wetting of the medical devices, the incision or the opening in the body through which

the catheter or other device was introduced into the patient's body. Although the medical supply materials used to make these makeshift coverings were often sterile, they were typically porous, water absorbent or water permeable materials, and did not offer protection against wetting or contamination.

5 In one earlier catheter cover made of a porous, water permeable cotton fabric, the cotton fabric was sewn into a two-walled pouch having 'hook and loop' type fastening bands (for example VELCRO™ brand fasteners) along two adjacent, outer edges of the cover. This known example is illustrated in Fig. 2. In this illustration, a catheter 1 extends outwardly from a patient's body, through an entry point 11 in the patient's chest 8. A sterile dressing 19 covers the exit site 11 and catheter 1, the sterile dressing securing the exposed portion 3 of the catheter 1 to the
10 patient's chest. Catheter tubes 7 extend outwardly away from the body, toward their distal tips 9. The hook and loop fastening bands 42, 42' and 47, 47' could be opened so that the exposed portion 3 of the catheter 1 could be introduced into the interior of the cover 41. The cover 41 was made of a breathable and permeable fabric, namely cotton. The upper fabric layer 43 was
15 sewn to the underlying fabric layer 44 along two adjoining margins. The two opposing edges 45 and 46 of the cover, opposing the two closed margins, were edged with hook and loop fastening features to allow the user to open the cover and insert the exposed portion of the catheter. In this device, the two edges 45 and 46 defined by adjoining hook and loop segments 42, 42' and 47, 47' defined a single opening. The cover 41, with the catheter positioned within the interior
20 space of the cover, would then be closed by engaging the opposing bands of the hook and loop fasteners (along 42, 42' and 47, 47'). Often a medical care provider would be required to use both hands to disengage the hook and loop fastening bands and thereafter remove the protective cover without tugging or dislodging the catheter. Medical staff, and those patients who were confident enough to remove the covers themselves, would often need both hands to
25 firmly grip and then carefully open or close the earlier protective covers including these hook and loop fasteners.

SUMMARY OF THE INVENTION

In one aspect, the invention includes a removable protective cover for an exposed portion of a medical device extending outwardly from a body. The outwardly extending medical device
30 defines a longitudinal axis. The cover comprises a housing that defines an opening along a single edge of the housing. The edge defines a line that intersects the axis. The edge may be sealed to enclose the exposed portion.

In one embodiment, the housing may include a pair of opposing walls that define a sealable pocket. The opposing walls may be made of one or more flexible materials, for example, one or more fabrics. The flexible materials may be impermeable to water, and contaminants including pathogens.

- 5 In a preferred embodiment, the edge may be operated between an open position and a closed position by use of a single hand. For example, a spring may be positioned adjacent the edge to releasably seal the opening.

In another aspect, the single edge lies in a plane. The edge forms a releasable seal when in contact with the body. The plane may include an adhesive suitable for contact with exposed
10 skin on the body. The adhesive may form a band that surrounds an entry point through which the medical device extends into the body. It is preferred that the adhesive secures the cover to the body, to form a barrier about the entry point.

The cover may include a display for treatment information. For example, the display may comprise a transparent pocket for display of a patient's name, special instructions or other
15 information relating to the patient's medical treatment. In another example, the display may be a surface on which ink writing may be applied by medical staff. Other display elements and techniques may be provided.

In another preferred embodiment, the invention is a kit including two housings used to cover an exposed portion of a medical device extending outwardly from a body. The first housing defines
20 an opening along an edge. That edge is sealable so that the exposed portion of that medical device is enclosed within the first housing. The second housing receives the first housing. Preferably, the second housing completely envelopes the first housing. The second housing is releasably secured to the body about an entry point through which the medical device extends from the body. One or both of the housings may be made from flexible materials such as
25 fabrics. The flexible materials are preferably impermeable to water and contaminants. The second housing may include a band for releasably securing the second housing directly to the body. For example, the band may include an adhesive suitable for direct contact with exposed skin on the body. It is preferable that the adhesive band be applied to the body in a manner that will provide an impermeable barrier about the entry point.

30 The entry point may be a small incision created during a medical procedure. The entry point may be partially protected with a dressing. Often the dressing will include gauze and other air permeable and water absorbent fabrics. Often the dressing will be air permeable, to allow

oxygen to contact the wound, to inhibit infection or other detrimental effects. In addition, the dressings will often include absorbent portions to allow absorption of fluids leaking or oozing from the surgically created entry point.

In some embodiments, the first housing may be visible through the second housing. For example, the second housing may be made from a substantially transparent material, for example, a flexible, transparent film of thermoplastic material so that the position and condition of the first housing may be readily determined, without having to remove or disturb the second housing. One of the first or second housings or both may include a display for treatment information.

- 10 In a preferred kit, the first housing will include a flexible band about the opening. The flexible band may act as a spring to bias the edge of the housing toward the closed position. The band may also include a deformable seal to tightly grip about the exposed portion of the medical device. The deformable seal may be provided by opposing segments that tightly mate or engage to inhibit inward migration of water and contaminants. One or both opposing segments
- 15 may be made of deformable foam having a memory so that preferably, the foam will return to its original state when disengaged from the medical device.

The protective cover of the present invention may provide one or more of the following advantages or other advantages which will become apparent upon a review of the present specification. By way of an example, one or more of the following advantages may be obtained:

- 20
- an easily removable protective cover may be provided to enclose an exposed portion of a medical device secured to a body;
 - certain embodiments of the protective cover may be removable with the use of a single hand;
 - certain embodiments of the protective cover may be made of water resistant
- 25 or water impermeable materials;
- certain embodiments of the protective cover may provide a barrier against contamination of the exposed portion of the medical device and/or the opening through which the device is introduced into the body;
 - a kit may be provided in which a first removable protective cover may be
- 30 used to enclose an exposed portion of the medical device, and a second

removable protective cover may be provided to inhibit contamination of an opening through which a medical device is introduced into the body; and

- one or more of these advantages, or other advantages, may be available to those who use or provide embodiments of the present invention.

- 5 The foregoing are only some examples of certain embodiments of the invention. Many other embodiments, variations and derivations will become apparent from a review of the entire specification, including the description and appended drawings.

IN THE DRAWINGS

- 10 Certain specific embodiments of the invention will be described with reference to the following drawings in which:

Figure 1 is a top view, in perspective, of a first embodiment of the invention partially enclosing an exposed catheter implanted in a patient.

Figure 2 is an enlarged top view of an earlier version of a catheter cover in the prior art, in partially opened position, exposing a partially enclosed catheter.

- 15 **Figure 3** is an enlarged top view of an embodiment of the present invention showing a self-sealing catheter cover.

DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS OF THE INVENTION

- A preferred embodiment of the invention is shown in Fig. 1. Specifically, in this embodiment, a kit is shown for covering a catheter 1 extending into a patient's body 2. An exposed portion 3 of the catheter 1 is covered by a sterile dressing 19 (including adhesive tape) secured to the patient's body. The dressing 19 is applied over an entry point (such as an incision) into the chest wall of the patient's body. In this example, the proximal tip 5 of the catheter 1 extends into the superior venacava 6 through which blood flows via the heart 4. Catheter tubes 7 extend into the interior of an inner housing 20. Inner housing 20 provides a clamping pocket to protect the distal ends 9 of catheter tubes 7 as further illustrated in Fig. 3.

When the catheter 1 is implanted in this manner, the distal ends 9 of the catheter tubes 7 would be exposed, on the exterior of the patient's body, perhaps covered with a dressing gown or a layer of gauze or other dressing material. The inner housing 20 may be applied to cover the distal tips 9 of the catheter 1 together with an additional dressing (not shown), if such an

additional dressing is present or desired. In the preferred embodiment as further illustrated in Fig. 3, the housing 20 is opened by applying pressure at opposing grips 24, 25 and squeezing apart upper edge portion 21 away from lower edge portion 23, to form a first opening 22.

5 Preferably, edge 21' is provided with a clamping feature, such as for example, two opposing spring members secured within upper and lower edge portions 21, 23. The spring members (not shown) may be secured adjacent edge 21', to bias the housing toward the closed position, so that the opening 22 is closed, and edge portions 21, 23 are securely clamped across tubes 7, thus covering previously distal tips 9 of the catheter 1.

10 In this preferred embodiment, the inner clamping pocket (or inner housing) 20 is provided with two opposing walls, specifically first wall 26 and second wall 27 secured together along side margins 31, 32 and along opposite margin 28. Information pocket 29 is provided on the exterior of wall 26 to display the patient's medical treatment information. That information may include the patient's name, personal information, information concerning drug dosages, or other medical treatment information. The information pocket 29 may be a transparent compartment that may
15 receive printed information on a card, paper or other device, for easy viewing by attending medical personnel. This display feature may be provided in other ways. For example, the medical treatment information may be supported on a writing surface applied to an outer portion of wall 26. In some embodiments, the display will be reusable, to allow additions or changes to the displayed information, and in other instances, the display may be designed for single usage.

20 One or both of walls 26, 27 may be made of transparent material. A variety of suitable materials will be apparent to those skilled in the relevant art. In some instances, it may be desirable to use a breathable fabric, such as a pretreated cotton fabric. In many instances, including preferred embodiments, it may be more desirable that the walls 26, 27 be made of an impermeable material to prevent contamination of the distal tips 9 of the catheter tubes 7.

25 In another embodiment of the invention, the opposing margin 28 may be opened and closed in a manner similar to the steps for manipulating clamping edge 21'. For example, in this modified embodiment, the opposing margin 28 will define a separate opening, fitted with a separate clamping feature similar to the spring members described above with reference to clamping edge 21' shown in Figure 3. In a preferred version of this example, the opposing margin 28 may
30 be provided with clamping features which mirror those features of clamping edge 21', to make the respective edges 21' and 28 interchangeable, or to allow access to the interior of the housing 20 without requiring removal of the housing 20 from the exposed portion of the catheter 1.

In Fig. 1, the kit includes both an inner housing 20 and an outer, or second, housing 10. In some embodiments of the invention, it may be desirable to forego use of the second housing 10. It may be useful to utilize only housing 20 to provide a protective outer covering over the exposed tips 9 of the catheter 1. In other instances, it may be desirable to forego the use of the inner housing 20, and to apply only the outer housing 10 over the exposed distal tips 9 of the catheter.

However, where a kit with two housings is used, or the outer housing 10 is used without housing 20, the features of housing 10 may be illustrated with reference to Fig. 1. As shown in Fig. 1, an outer housing 10 is attached to the chest 8 of the patient's body 2 using an adhesive band 12 which surrounds an opening 16 into the interior of the housing 10. The interior of the housing 10 defines a pocket 14 to receive the housing 20, which in turn surrounds the exposed tips 9 of the tubes 7. The pocket 14 is bounded by an upper wall T and a lower wall B, the lower wall being shown in an intermediate position between upper wall T and the patient's chest 8. The upper wall T is bounded by lower margin 17, side margins 15, side portions of the adhesive band 12 and upper margin A as shown in Fig. 1. The lower wall B is bounded by lower margin 17, side walls 15 and inner edge portion 13.

When first manufactured, the adhesive band 12 may be covered with a removable protective film or layer that may be peeled off, to expose the adhesive band, for attachment to the patient's body. Of course, other variations will be readily apparent to those skilled in the art after reading this specification.

With reference to the example in Fig. 1, the adhesive band 12 lies in a single plane, to define a single opening 16 to the interior pocket 14. When viewed from a side elevation, the single plane defines a single edge (or for example, a single line) for access to the opening 16. When applied over the exposed portion of the catheter, and when the housing 10 is so viewed from its side, the single plane intersects the catheter across the longitudinal axis of the catheter.

The adhesive band runs along side band portions 12, inner edge portion 13 and along upper margin A. The opening 16 is sealed against the environment, by inserting the exposed portion of the catheter 1 (either with or without the first housing 20) and then applying the adhesive band to the patient's skin so that the adhesive band sticks to the patient's chest.

The housing 10 may be made from various materials that would be suitable for use in medical applications. For example, the walls T, B may be made from the same or different materials. One or both of the walls may be transparent, to allow easy viewing of the interior of the housing,

including the contents of pocket 14. Walls T, B may be made of impermeable materials to prevent contamination of the exposed distal tips 9 of catheter tubes 7. It is also preferable that the materials of construction will be selected and manufactured so that the resulting article will be "sterile". The size and shape of the opening 16 may be designed to allow a user to place the opening 16 of housing 10 in a position above an entry point into the patient's body (similar to another entry point as shown in Fig. 1.)

In some instances, it may be desirable that the housing 10 be made of a fabric which prevents entry of water droplets (for example when the patient washes or showers) but will be sufficiently permeable to allow air (and most importantly oxygen) to reach the entry point, to inhibit infections or other harm to the underlying tissue. The choice of fabric or other materials of construction will depend on a variety of factors which are understood by those skilled in the art.

Housing 10 may also be provided with a display for medical treatment information, similar to the display features described above with reference to housing 20, including with reference to Fig. 3.

Housing 10 may also be provided with a second distinct opening at lower margin 17. For example, in some embodiments, it may be desirable to allow access to the interior of the housing 10 without requiring the user to disengage or remove the housing from the patient's chest. In this modified embodiment, it may be desirable to provide a reusable opening and closing feature. For example, the lower margin 17 may be provided with a closing clamp similar to the clamping feature described with reference to clamping edge 21' of housing 20. Of course, other suitable closures may be provided if desired. For example, where the housing is made of two thermoplastic film layers, the supplementary closure at lower margin 17 may take the form of interlocking zipper-like track members (of the kind shown for example in Canadian Patent 1,062,207 issued September 11, 1979 entitled Reclosable Plastic Bag Construction Made From A One Piece Extrusion).

Although the foregoing examples have been described in terms of two sided pockets, other shapes and configurations of protective housings and covers are possible. In addition, although the examples were described in terms of medical treatments of humans, certain embodiments of the invention will also be useful with medical devices used in certain veterinary applications.

The invention also includes a method of providing a resealable protective cover for medical devices. By way of example, the invention includes a method of providing a removable, resealable sterile protective cover for an exposed portion of a medical device extending along a

longitudinal axis from a body, the cover comprising a housing, the housing defining an opening along a single edge, the method comprising:

introducing the exposed portion across the single edge, into the housing;
positioning the exposed portion of the medical device within the housing so that the edge
5 intersects the axis;
sealing the edge to enclose the exposed portion within the housing; and
securing the housing relative to the body.

In the method of the invention, the housing may be secured relative to the body via an adhesive band. The adhesive band may be provided as a layer or coating of adhesive material that is
10 pre-applied along the single edge. In other embodiments, the housing may be secured relative to the body by releasing a biasing member positioned along the single edge to engage the exposed portion of the medical device.

The foregoing are examples of certain aspects of the present invention. Many other embodiments, including modifications and variations thereof, are also possible and will become
15 apparent to those skilled in the art upon a review of the invention as described herein. Accordingly, all suitable modifications, variations and equivalents may be resorted to, and such modifications, variations and equivalents are intended to fall within the scope of the invention as described herein and within the scope of any issued patent claims.